LAW AND POLICY IN AN ERA OF CYBORG-ASSISTED-LIFE[1]

THE IMPLICATIONS OF INTERFACING IN-THE-BODY TECHNOLOGIES TO THE OUTER WORLD.[2]

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Abstract— Medical technology verges on incorporating directly into our anatomy processors with the computational power of the famous Watson IBM computer and Internet-like communications. As the size of computers spiral downward, their wholesale use (as well as RFID-type technology) will extend lifetimes, enhance our intellect, and assist in controlling technology outside the body via digital I/O and thought. This includes the eventual merging of synthetic DNA and artificial intelligence that together will bring new diagnostics, medical treatment and smart nano-prosthetics well within the horizon of the next generation. A prosthetic genome hastens the day when enhanced life forms, such as human organs, can be made entirely from a fusion of living organisms and non-living materials. Wide-spread diffusion of this technology into populations risk creating a world of "haves" that can afford and "have nots," that cannot afford enhanced intellect and longevity. Without changes to current U.S. patent law, commercial interests might jeopardize our well-being through patent monopolies, market forces might squeeze out efficiencies at the expense of performance and reliability, and wrongdoers might dare to unleash digital viruses into a world filled with anatomically installed biomedical devices receptive to Internet-style communications. Overtime artificially altered and controlled metabolisms may begin to alter the progression of natural biological evolution and force an examination about what the notion of "human" means in the age of human cyborgs.

Keywords- ***Technology Law, science policy, cyborg, transhuman, telemetry, molecular computer, human enhancement, RFID, synthetic DNA, artificial intelligence, evolution, technology ethics.***

I. INTRODUCTION

This paper discusses aspects of the technical and consequential legal implications of the proliferation of implantable in-the-body technologies and their connection to commercial, medical and governmental networks. The pacemaker serves as the pioneer in this development, using microprocessors and telemetry.[3, 4] I posit that over time populations in developed nations will increasingly resort to implantable technologies, not only for critical life saving devices, such as the pacemaker (currently used for a couple dozen medically therapeutic interventions),[5] but to improve the quality of lives health-wise, intellectually, socially and commercially.[6] These devices will represent a convergence of internally integrated technologies such as represented by nano-bio-information-cogno (NBIC),[7] and more specifically advancements in silicon-based platforms, nanotechnology material-platforms (e.g., wafer-thin graphene (carbon) with MoS_2 (molybdenum disulfide), and biotechnology platforms (e.g. synthetic DNA), communicating via telemetry within a framework of an interior intranet to an exterior Internet.[8]

The 2010 global market for microelectronic medical implants, accessories and supplies has been estimated at US$15.4 billion and by 2016 forecasted at US$24.8 billion.[9] Even at these revenues, medical, commercial and personally enhancing in-the-body technology has yet to become a widespread phenomenon. Nonetheless progress in smaller, faster and computationally more complex processors augurs a future where humans will place greater reliance on computers to control the world of their anatomies using telecommunications to the outer world of servers.[10] Ray Kurzweil, a leading futurist, recently opined that implantable health related devices would be seen by 2020 and a decade or two later will go beyond medical appliances.[11] And, when such a shift in application occurs, then it is plausible that many devices will undoubtedly affect population lifestyles, health, employment opportunities, commercial access, liberties and fairness.[12]

Finally, although many concerns may be ripe for discussion as to the implications of implanted/telemetry technology, I limit my comments to regulation, ownership and economic fairness, three issues that I believe would be high on most lists in consideration of research, discussion and policy formation.[13]

II. PLAUSIBLE TECHNOLOGY TRAJECTORY

According to Moore's law, the number of transistors in integrated circuits doubles approximately every 24 months

and computer power doubles about every 20 months. Within this constraint, we can estimate that for Moore's law will begin to falter soon after 2020,[14] but computer processors will continue to shrink to the size of a bacterium, 2 microns or micrometers (μm) long and 0.5 μm in diameter, with a cell volume of 0.6 - 0.7 μm^3, while increasing their processing speeds to upwards of 10^{16} (10 quadrillion) operations per second, referred to as flops. This small size will allow computers to live both within and alongside the human cell. The level of 10 quadrillion flops exceeds the processing rate, at roughly 10^{15} flops, of the human brain. This will permit adjuncts to memory to coexist within our bodies,[15] providing IBM Watson-like artificial intelligence to be accessible as much as it is reachable in hundreds of consumer products. Some computers will control microelectromechanical systems (MEMS), such as nano-sized motors that will range in size from 10^{-9} m (a few hundred atoms across) to 10^{-5} m —the diameter of a white blood cell. These traveling nano-bots will course through arteries and cellular membranes to deliver drugs and destroy pathogens. It is conceivable and likely that these computers will be equipped to communicate with the outer world.

Current technology employed for health-based reasons use RFIDs (radio frequency identification), microprocessors and drugs. By 2020, experts predict that The Internet of Things,[16] largely RFID, will connect 100 billion identifiable objects to the Internet,[17] many of which will be implanted RFID-like devices as well as more sophisticated anatomical devices.[18] As RFID technology and sophisticated processors combine to actualize the vision of widespread use of implantable/telemetry, 4G networks and successors, with gigabit bandwidth backbones, robust networking infrastructure, high-speed relays and unlimited power with recharging capabilities will serve as the medium through which feature-rich anatomical smart prosthetics operate.[19] In the next stage of advancement, the functions performed by these devices will be down-sized through progress in synthetic DNA, molecular computational devices, and nano-sized processors, deployed alongside, and within cells and organs as permanent non-organic, internal adjuncts to our anatomy. Applications will be in the realm of nano-prosthetics, nano-stimulators/suppressors, artificial organ processors, metabolic and cognitive enhancers, and permanent diagnostic tools to ensure our physical and psychological well-being as we head toward a practically interminable lifetime.

The three important drivers behind electrical control implantation are: (1) bioengineers are reaching a tipping point successfully converting computer technology into lifesaving and life enhancing products; (2) computers and their software, the backbone for these products are becoming ever more computationally sophisticated based on the accumulation of scientific knowledge; (3) between 2012 and 2020 processor speeds will increase from an already astounding 40 billion flops to 330 billion flops; (4) and the substrates, that is the material part of the computer, now measured in micrometers or the size of blood cells, will dive deeply into the realm of wafer-thin graphene (carbon) and MoS_2 (molybdenum disulfide) measured in nanometers, just a few atoms wide.[20]

III. APPLICATION SCENARIOS

In perhaps the first in-the-body/outer-body telemetry, a radio pill known as the Konigsberg telemetry pill was ingested in the early 1960s by patients to record their internal temperature and then transmitting the data to a receiver to be analyzed by medical professionals.[21] In 1991, Jerome Schentag invented a pill that when swallowed allowed it to be tracked electronically as it progressed through the alimentary tract and, upon reaching a specific site, was remotely triggered to release a dosage of medication.[22] Since then, small devices have attached video cameras to such pills to record the stomach and intestines, while other devices detect conditions and send signals to an electronic patch on a patient's skin that in turn transmits information to a computer. Much of this progress during the past 50 years has gone relatively unnoticed by our citizens.

Today's implanted E-chip, chiefly RFID technology is used for identification. RFID chips are used to locate missing children or Alzheimer victims, and in combination with other forms of sensors, help monitor diabetic glucose levels.[23] In 2004, upwards of 160 employees in the office of Mexico's attorney general, had implanted microchips as a requirement for gaining access to secure areas.[24] That same year a Barcelona nightclub offered VIPs a microchip for implantation under the skin, which when scanned would guarantee entry and provide access to a debit account for purchasing drinks.[25] Soon the idea was used in Rotterdam, Holland.[26] One might predict that in the near future, other types of E-chips will automatically debit bank accounts, reward shoppers to stop at selected points of purchase, verify "no fly lists", replace credit cards and do not resuscitate (DNR) bracelets as well as supply employment verifications. The list is virtually unending.

We might anticipate that traditional medicine, even the ever-improving pharmacology, will be replaced or augmented by implanted/telemetry bio sensors, organ stimulators and pumps, utilizing the materials, electronics, computer processors and inter/intra-body communication networks to enhance or replace failed human organs. Physicians are already developing deep brain stimulators to adjust thinking and emotions.[27] It is being considered that this therapy will be made available not as pharmacological products (such as Prozac) but as cybernetic packets that reprogram operating systems (the basal ganglia, thalamus, subthalamic nucleus, globus pallidus, internal capsule, nucleus accumbens) specific to brain functionality. Though we can only speculate what this vast technological territory might look like, seeing where we are currently situated provides a clue as to what lies ahead. Material science (nano-technology, synthetic DNA, and non-genomic polymers), electromagnetic imaging technology to reduce the size of manufactured structures, and quantum physics technology will combine to

allow continuing declines in component size and improvements in sensor sensitivity and computational power. These physio-chemical advances will complement the growth in the bio-chemical technologies and the unlocking of the inner workings of the brain, genome, and epigenome.

In the next few decades physio-chemical advances in materials will create roving nanobots and molecular computers that will blur the boundaries between natural and synthetic molecular systems. Some of these systems will operate autonomously to keep biological processes highly tuned. Others will communicate inner body data to larger external data bases where merging of data from all other similarly bio-equipped individuals will insure everyone is linked and synced-in with the latest trends in wellness remediation. Advances in bioscientific research will contribute to extend life through genomics, epigenomics, and proteomics, where delivery systems of older drug prescriptions will be replaced by digital applications or APPs transmitted over bio-information highways to all individuals possessing certain computer-driven, bio-operating systems that can interface directly with the anatomy's subsystem.

Presently in-the-body medical devices capable of maintaining a bi-directional radio communication with a remote computer utilize the Medical Implant Communication Service frequency band between 401 MHz and 406 MHz. The maximum power transmission is quite low at 25 microwatts, providing a range of a couple of meters to reduce the risk of interfering with other users on the same band. The maximum bandwidth is 300 kHz, which makes these devices low bit-rate systems, compared with WiFi or Bluetooth. Nonetheless these devices are capable of transmitting to a receiver that in turn is connected via USB to any computer ready device through local area networks (LAN), wide area networks (WAN), and access the Internet. This will likely be the channel where diagnostics for hardware, software, and biological functions will be routinely run on patients.

Systems of medical devices that interoperate in the single-person environment can be divided into three areas: 1) sensors, electrodes, stimulators, actuators, and pumps that deliver therapy and make measurements; 2) network architecture, including telecommunications that interconnect the devices both within the body and to the outer world; and 3) mechanisms to program applications using the interoperability architecture. These interoperable systems will allow for sharing of information throughout networks both wired and wireless. Therapeutic devices will be tailored to a range of specialized clinical situations, home care, hospitals, the battlefield, portable applications and doctor visits.

Until the three-quarter turn in the twentieth century it was common for doctors to visit elderly patients where they lived. This changed, when in the latter quarter of the last century, elderly patients were seen almost exclusively in a doctor's office. However, with the advent of implantable/telemetry, reactive medicine will take medical examinations to a new level where patients will login to their home computer and have all the benefits (and more) of a visit to the doctor's office. One of the added advantages to having a router/modem feature as one of the technologies embedded in the anatomy will be access to medical care at any time, day or night, simply through a wireless connection. By answering a series of questions posed by an expert computer system, symptoms will be narrowed to a range of maladies and patients will participate in their own diagnosis. To the extent a doctor's intervention is required, a doctor best equipped to deal with the intake diagnosis will be either contacted or a referral made by the computer.

A worldwide grid will "tune" in on millions of individuals feeding searchable public health databases using a patient's anatomical data (perhaps anonymously) to update an expert system. On the surface, the process will likely resemble an online differential diagnosis website, where today one can subscribe, but without the real time (second-by-second) input from millions of medical devices from the vast general population. Large amounts of data, collected from millions and eventually billions of people will not only improve a single person's health, but the health of entire populations. When implantable/telemetry devices serve as input, this stage of public health service will be completely "predictive, preventive, personalized, and participatory"—, all without the patient being aware of data being transmitted and collected.

A medical community with ready access to the body through electronic communication mediums will change our once direct patient-doctor relationship into one where patients will interact with on-line physicians and expert systems. Let us consider two hypothetical scenarios. First, it is likely that a widespread use of in-the-body computers and communication devices will allow examinations from standard computer terminals or even smart phones.[28] Doctors may look at the data collected during so-called medical examinations hours or days after the fact, unless alerted by an "intelligent agent" that they look sooner. In most cases a computer will analyze the data well before a doctor sets eyes on the raw data. In some ways this is not different from the local medical laboratory that analyzes blood and reports the results to the physician—, but on a different scale. And, in time, as the computers get "smarter," there may be a tendency to relegate more and more decision making to the computer's "intelligent agent," removing in some respects the physician from routine doctor's orders or prescriptions.

Currently, timely prescription drug refills is largely relegated to automated inventory systems that keep track of when the supply runs out, send out a robo-call, which when positively responded to, sends the refill order to the pharmacy and informs the patient when the order will be ready for pick up. If we speculate that in the future drug supply might be stored in a miniature "warehouse" within an anatomical cavity, it can be assumed that even under current state-of-the-art it can be delivered to the precise location upon receiving a signal from a drug management system.

The second way in-the-body technology will impact medical care is through the anatomical access that telemetry provides. Telemetry systems available today permit physicians to maintain and alter the rates of drug deliveries or the rate of electrical current excitation that a device such as a pacemaker

or brain implant delivers. Assuming that implantable/telemetry technology follows essentially the same track as the personal computer, the medico-technological communities will eventually handoff control over these devices to remotely located servers. As we operate in a cyborg-form a constant stream of tweets carrying sometimes vital and sometimes non-essential queries will keep our platforms responding to the autonomous external world (much as our Internet browsers do now). Most of us have woken to the morning message that our computer has been recently updated.

Companies will need to address the challenges of interconnecting medical devices from different manufacturers, into a seamless medical device "plug-and-play" network. Products historically vertically integrated by a single manufacturer will become components in a larger multi-vendor system, where larger corporations, will offer bundled services, as do the large telecoms today for smart phones. They will establish call centers to service the extraordinary number of individuals utilizing implantable technology, which will inevitably spawn a host of complaints that the device or system does not function according to expectations or specifications. We might anticipate based on today's model that as do call centers today, relatively unskilled operators will attempt to remedy problems before sending them up the chain to experts.

The Medical Device Security Center operates as a private partnership between Beth Israel Deaconess Medical Center, Harvard Medical School, the University of Massachusetts Amherst, and the University of Washington and has as its mission the balancing security, privacy, safety, and effectiveness for next-generation medical healthcare devices. In one study researchers investigated whether hackers could gain wireless access to combination heart defibrillator/pacemakers that allow doctors to monitor and adjust operating parameters remotely.[29] The experiment simulated the effects of a "hacker" using a readily available commercial programmer and a software radio that can be purchased on eBay. The test successfully demonstrated that a hacker could reprogram the device, shut it down, deplete its battery, or deliver jolts of electricity that could be potentially fatal to a would-be patient. The researchers obtained personal patient data (name and diagnosis) and medical telemetry data by snooping on signals from the embedded radio. In 2011, an independent security researcher revealed before an audience at Black Hat 2011 vulnerabilities with the implanted insulin pumps worn by diabetics, which would allow attackers to remotely control dosage rates.[30] The ability to hack into in-the-body devices presents a life-threatening breach that might not be merely directed at a specific victim, but to an entire population, ordinary people and world leaders included.

IV. REGULATORY CONSIDERATIONS

In considering policy and law needed to govern implantable technology having telemetric features, one must first address what is meant by "the law." Law deals with both subject matter and process, which divides along the bright line that separates civil from criminal law. In the U.S. and countries that have a system of common law, the foundational corpus originates in legislation and judicial decisions. On the civil side, a body of law also exists in the agencies and departments that administrate, regulate and adjudicate the broader legislative and case-based mandates. Patents, prescription drugs, medical research, telecommunications and medical devices are examples of technology that is in one or another way regulated by agencies. However, individuals that have complaints about products, as for example a warranty or injuries as a result of a product defect, are matters typically addressed in civil suits.[31]

Much international regulation is not driven by local statute, but via treaties and their enforcement as to subjects such as intellectual property protection and standards setting as addressed by WIPO, TRIPS and WTO.[32] On a domestic level, Congress may establish agencies, such as the FDA to police such things as implantable/telemetry and to regulate enhancements, medical or otherwise, if they, like prescription drugs, can only be provided through government qualified or licensed entities, such as physicians, hospitals or special techno-hospitals. On the other hand, non medical uses could be exempted from regulation, as for example implantable RFID for identification or for commercial uses that may replace such things as a smart credit card.

A legislature is motivated to address a set of existing conditions and does not generally enact statutes for the purpose of affecting hypothetical occurrences and consequences. With the foregoing in mind, the specific laws that might be necessary in the administration, regulation and adjudication of in-the-body/telemetry medical and nonmedical applications where large populations are affected cannot be predicted with any degree of confidence at the moment, in part because law is backward looking. However, in conjecturing what we might see in a future where implantable/telemetry devices proliferate within a population, we can look for cases analogous to situations that could be reasonably exist in such as society.

In the 1800's a celebrated case dealt with a landowner and the responsibility he had for maintaining a potentially dangerous body of water on his land. In that case a reservoir flooded a nearby mine.[33] The court held the owner responsible for the consequences of the act regardless of how carefully he had maintained the body of water. The mere possession of such a potential force was enough to hold the defendant accountable for its release. This case fundamentally established the concept of strict liability, which during the last century has become the underpinning for the product liability cause of action, where evidence of a requisite standard of care is not at issue, but simply whether the product is dangerous. In today's world, the mine of yesteryear has been replaced by the technology of today. What happens when an in-the-body prosthetic update broadcast to millions of people goes haywire or perhaps contains a virus? Presumably, those who control the technology must be held accountable for the consequences actions and failures to act. But, this is obviously not yet black

letter law. It is often a law based on principles of product liability.

Product liability litigation involves lawsuits that allege personal injury as a consequence of the product itself or negligence on the part of the supply source, manufacturer, distributor, or the entities that install or maintain the device. For example, would a manufacturer and supplier of pacemakers be liable if someone were to hack into a device causing harm to the patient? It is not clear. To what commercial, medical and legal standard will those who supply enhancements be held? Suppose the product did not relate to one's health, but an enhancement for purely elective reasons, as for example, the guaranteed gain in something like human intelligence were to fall short, or the advertised extended human lifetime were off by a decade or two? Would that alter the legal case? Presumably, current warranty law would be sufficient robust to fairly litigate such a claim.[34]

The nearest analogs to cases that would entail large numbers of people injured by a faulty implantable/telemetry product would be the mass tort cases involving such things as asbestos, cigarettes, large scale food adulteration or malfunctioned medical devices. In some cases the class is relatively small, such as occurred when salmonella-infected individuals who had eaten contaminated cantaloupe.[35] The infection affected several hundred people, with three deaths, but the lawsuits were primarily of single individuals suing producers or sellers, in suits sounding in product liability: breach of warranty, negligence, negligence per se, and strict liability. It would not seem that future cases in implantable/telemetry cases would differ in substance, but classes of injured might run rather than hundreds into the tens of thousands. If injury on so grand a scale were to occur, two possible routes might be taken to adjudicate cases. The first is the mass tort class action civil suit, which depending on size of the class, complexity and damages might be litigated using the historically reliable model employed by the plaintiffs claiming to have been injured by inhalation of asbestos or cigarettes. In the other model, government could pass legislation setting up an administrative agency with scheduled compensation, such as is done in worker's compensation and similar compensatory award schemes.[36]

More closely related to the technology at hand is the pacemaker, in which wires failed to transmit current from the generator/computational device to the heart. The "J" pacemaker leads polyurethane insulation failed, which allowed the lead to puncture heart or aorta. At least 456 individual cases involving this claim were consolidated into nationwide mass tort class action claiming negligence, strict liability, and punitive damages. In August 1998, a federal court judge approved a $57.2 million settlement. The settlement provided up to one-million dollars for each individual who died because the pacemaker leads broke or because of removal or replacement surgery and for those that survived, provided for medical monitoring costs to patients with the subject leads.[37]

Policy makers, courts and legislators only begin to consider issues that emerge from how such devices are actually applied in the marketplace. One might ask the extent to which the current regulatory process can address safety and efficacy related to implantable devices and telemetry on a large scale. The time between technological advance and policy advance appears as a repeating feature throughout history, although, perhaps now time has come to anticipate potential problems that lie ahead in regards to implantable/telemetry. To this end, various commissions and private institutions attempt to anticipate problems rather than wait until they are upon us.[38]

When Congress does not explicitly act, federal agencies pass rules having the effect of law.[39] This has been the practice affecting patenting bioengineering artifacts such as stem cells or gene sequences.[40] In other instances, where technology creates questions neither administrator nor legislator can answer, boards or panels are established (e.g. the Human Embryo Research Panel that considers the ethics of embryo research). As in-the-body technologies communicate with the outer world in greater numbers, professional organizations will further develop communication standards and protocols, fault tolerance (redundancy), practical levels of encryption (to prevent "hacking"), and regulations that impose restrictions on entities that control data collection and operate communication servers.[41]

Agencies having standards established, presumably the FDA (in the US) in the case of combination medical devices will turn attention to the regulation of implantable/telemetry related software, controlling who will supply medical device software, software updates, or who decides when software subscriptions can run out. These matters invariably implicate insurance, health care, patents, copyrights, licensing, product safety and other consumer laws. There will be likely an enforcement function to police as well: viruses, bots and spam, and other evils and ills that befall the average computer user today, but that in the future may release a deadly computer virus into a medical network, one that causes vital, life-preserving apparatuses to malfunction causing injury and even death. What kind of policing system is needed, and what are the costs of defaults, of violations in security? And for those that perpetrate crimes against in-the-body devices, what penalties? Concern over hacking into medical devices is not hypothetical. It is not clear that any U.S. agency is prepared to undertake the burden of these issues.

These kinds of activity are in some measure proscribed by criminal statute. Criminal activity through the use of computers including the Internet takes many forms that will be applicable to in-the-body/telemetry devices and systems, such as "hacking," to remotely access a secure computer or Internet location or intercepting an electronic transmission not intended for the interceptor.[42] There is no evidence to suggest that the criminal law will not flex its muscle to deter and punish for criminal behavior that actually or potentially harms individuals, as society increasingly incorporates technology into the human anatomy. Although, the FDA monitors recalls on products that contain errant components including software, until now few instances have been reported of Internet and software related willful

misconduct or malfeasance resulting in bodily injury or death. [43] However, currently little enforcement (state or federal) is apparent in areas of software piracy, knockoffs, unlawful upgrades, updates, downloads, hacking or virus dissemination. Whether policing can measure up to the task of enforcement is yet another question.

The FDA deals with combination products which include, among other things, products largely comprised of two or more regulated components, i.e., drug/device, biologic/device, drug/biologic, or drug/device/biologic, that are physically, chemically, or otherwise combined or mixed and produced as a single entity.[44, 45]

The FDA must position itself to address the world of implantable/telemetry devices integrated into an external world of telecommunications on a large scale, for devices used for medical prescription and for non-medical enhancement.[46] Additionally any future regulatory scheme must consider that unlike implanted medical devices that today largely run in a closed system software process, the future implanted/telemetry device will be connected to remote servers that will play an operational role in updating software, much as occurs in personal computing, today.

The potential for harm brought about by in-the-body computers connected to external databases raises the question as to who will regulate such technology—the medical community, government or a self-regulated industry. [47] Clearly there are safety and privacy issues in the telecommunication of medically sensitive data. [48] Private medical data benefits the patient or in the case of a non-medical application the enhanced user, but is also useful to the manufacturer and those institutions on the receiving end of such data. Data miners, such as search engine companies do not manufacture the devices used to access search engines, but data mining is essential to their success proposition. Manufacturers on the other hand, armed with certain information can improve the product and make it more reliable and more economical to produce.[49]

V. OWNERSHIP-INTELLECTUAL PROPERTY[50]

Prosthetics such as dental bridges, pacemakers, or those that replace a limb or an organ embody two kinds of property interests. First is tangible personal property, which grants the right to do with the article what the owner desires. He or she could sell the item as freely as selling a table or chair. The exception is that body organs (e.g., heart, kidneys, liver, lungs, pancreas, intestine, and thymus) and tissue transplants (e.g., bones, tendons, cornea, skin, heart valves, and veins), whether in a body or awaiting transplantation, are not allowed to be sold in the United States.[51] A second kind of property, relevant to this discussion, is intellectual property, an intangible property right, which applies to the trade secret, invention or tangible expression (such as software) that underlies a product or process. [52] The owner may assign ownership of the intellectual property or they may sell the tangible product or both, because they are, under law, deemed separate things. Another possibility is that rather than assigning or selling ownership, they may license the intellectual property for some purpose. What is said about licensing applies to computers components and software, and hence to the medical devices that constitute many of today's more sophisticated prostheses. Title to the intellectual property embodied in a prosthetic does not generally pass to the consumer.

A quarter century ago most of our current high-tech products did not exist. The same thing can be said about much intellectual property law. But, where technology seems to rationally develop, or presents an organized evolution, the law does not always evolve so neatly.[53] In trying to keep up with the progress, copyright, trademark and patent law has undergone dramatic change in the recent past. These intellectual property areas are being augmented by newer legislation such as the Electronic Communications Privacy Act,[54] and the Computer Fraud and Abuse Act,[55] that provide civil penalties for violations that would carry over into implantable/telemetry technology, as well.

As in-the-body technology becomes as common as body piercing, the law needs to establish clarity on ownership and control of the implantable technology, not only for addressing performance and warranty issues, but intellectual property issues, such as patent/copyright licensing, to determine rights to access for purposes of upgrading or repair. Current explosive technological growth, which includes the pharmaceutical and medical device industries, distinguishes itself from the past by the highly competitive immediate monopolization of ideas behind each new technology. For example, the number of patent applications filed in the U.S. has jumped from 177,830 applications filed in 1991 to 535,188 in 2011. This is only explained by the facts that more than any time in history, patents epitomize the currency of competition, and thus significant economic control over the distribution of products.

Accessibility to implantable technology on a large scale, for a multitude of uses, from medical necessity to elective enhancements, would likely not be owned in the traditional sense, but licensed, and in many important respects what a user might be able to do with the device, limited by copyright and patent monopolies, which manufacturers and providers typically impose. The notion is analogous to one's right or lack thereof to make derivatives of software, because the ownership is governed by an owner's copyright. One result would be to subject users to license fees, renewals that could only occur at the behest of licensors and for a fee, and express permission of the licensor before undertaking any repair or upgrading of the devices.

Property in the computer age takes on intangible features that heretofore were non-existent or not essential to a determination of individual, commercial or societal interests. This has led to an upheaval in the allowance of business method patents under U.S. law.[56] Consider again, the parallel to implantable technology is that most system operations from the implantable within the anatomy to the network gathering and processing of information will be amenable to patent

monopolization since inevitably it will, by definition, constitute a business method under existing patent law.[57]

Examples of intangible property might be the network that serves as the link between individuals and a collection of processors or the databases used to keep track in real time of a particular abnormality. Databases of this sort raise issues as to ownership of the information, privacy concerns, duties, obligations, liabilities to various constituencies, i.e., individuals, corporations, governments. Who will fund, own and thereby control the databases that communicate with in-the-body processors? Under what circumstances might service to the sensor terminate or be disconnected from a vital database or server on the network? Who will control the network insofar as maintenance, updates and security? One might consider myriad possibilities along these lines. The convergence of computers, communications and humans at the anatomic level will alter the world as we know it. The first, by virtue of the society we construct and the second by the kinds of technological artifacts we invent and need to protect ourselves against.[58]

In fact, intimate knowledge of a product or process is generally kept secret and remains secret, indefinitely, erecting impenetrable walls that prevent all but the hardiest competition from learning. Especially in technology law, where the property right at stake does not reach into the public psyche, much about the product's impact on society depends on the protection of its proprietary methods, and more specifically such things as the particular recipes where drugs are involved or algorithms where software is involved. To what extent does this impact a consumer whose life via implantable/telemetry is integrally connected to operating systems beyond comprehension because the technology is kept secret?

Courts and policy makers see the matter as one of economics. In the case of inventions that are life-sustaining, policy makers should take a fresh look at what ownership means and consider reforming the intellectual property laws to serve not only the commercial interests but the interests of the patient-consumer. After all, patents represent quasi–public interests, however, historically in the U.S., the matter of patents involving public interest versus private interest has been considerably more divisive and more stubborn in coming to a resolution (perhaps due to a U.S. libertarian and conservative provenance).[59]

In the cyborgization property sphere, diverse influences work their will on nascent policy and legislation. Yet, as the subject deals with economic interests, the wind blows predominantly in the direction of the corporation. Some corporate goals may align with the bodies of common ideals or ideologies.[60] Clearly, the interests that represent mainstream society may not always translate well into corporate interests. We see this in regards to environmental, health care, and tax laws. Those that stand to gain (i.e. corporate and other special groups) move in lock-step to influence legislative offices and the halls of justice. When it finally matures, that is when it reflects the adopted practice of a large segment of the population, cyborgization property law is likely to be a subject that raises more questions than can be answered by black-letter law. As such, it might be easily misunderstood and manipulated for the few who stand to make the most of legislation, even when the best interest of citizens point in another direction.

Ownership in the intellectual property will affect availability, price, performance, safety, and choice. Without regulation, commercial interests might well run counter to bioethics, raising issues in autonomy and distributive justice, primarily when the lack of affordability restricts access. This effect is not much different from the experience some have when they discover they cannot afford medical treatment or drugs: deprivation may mean the difference between life and death. However, implantable technology will not only affect those who are in critical need of the technology, but will affect those who may depend on its access to maintain their standing in a community of peers, enhanced lifestyles, extended lifetimes or to afford equal opportunity, notably in employment.

No single unified system's theory exists that considers invention on the level of motivating factors, economic effects, and societal goals—including the relatively new ethics of cyborgization. Invention itself embraces a universe of art, economics, psychology, science, and engineering. Before a theory of Keynesian economics existed, we had a fair idea of such concepts as systems of labor, capital, supply, and demand. Such a lucid prefatory structure for intellectual property law, especially in consideration of a future cyborgization of technology has not been established. Part of the problem in achieving this objective is that intellectual property deals with political rights of the individual and with other fundamental values and prescriptions for society, as mentioned throughout this paper. In cases where the technology has profound implications for social justice, we need to be especially mindful that without a theoretical underpinning, we often make arbitrary judgments that in the end prove counterproductive to humanitarian interests.

VI. ECONOMIC JUSTICE

As technology is applied to improve aptitudes, skills and life spans, we risk creating a world of "haves" who can afford and "have nots," who cannot afford the latest innovations. The situation would follow conventional prescription drug patterns, where some "treatments" would be available to most, a smaller number of "treatments" to only those who can nominally afford them and finally a select few "treatments" that are cost prohibitive to the vast majority of the population (other analogies might be drawn from disparate and unequal educational opportunities).[61] Some computational processing therapies might not have a health-related purpose but rather aim to provide a greater level of intellectual quickness or greater access to commercial opportunities. Part of what will distinguish the future human having implanted

computational devices from a population that does not will be that the new features and enhancements can connect to the Internet, opening vast benefits and consequent potential detriments.

Undoubtedly there will be significant individuals or entire populations, who will not have access to a world of bioengineered implants/telemetry for medical necessity, let alone enhancements to intellect, longer and healthier lives and improved skills. As such we need to begin a conversation that reevaluates the implications ahead for a society that espouses principles for distributive justice. The inequitable distribution of cyborgized property may affect each of us and certainly our progeny—just as the inequitable distribution of health care, education, clean air, water, water rights, or land does to those that live among us presently.[62] As outlined above, it needs to be decided whether any corporation, institution, or individual should have the right to private ownership of certain forms of cyborgized property—most notably, life saving devices (including process software) and selected methods of extending life and enhancing intelligence or skills.

As a society transitions to an in-the-body dependence on technology, perhaps at the top of anyone's list of inquiries would appear: at what point will "attitudes about what the notion of 'human' means" begin to evolve, or stated slightly differently, will technology conserve our current human form or serve to evolve human form into a new construct?

CONCLUSION

Future implantable/telemetry raises policy questions beyond law and regulation. For children being born today, the quality and the extent of their life will be driven as it has been by genes cast over 3.5 billion years, but also, in a significant way driven by the circuitry of new technology.[63] It would not seem preposterous to imagine that in time the human form will transcend historical biological limitations and meld into technology such that *Homo sapiens* of 2013 will be considered by future generations as inferior unaltered (unaugmented) creatures. Other than that casual observation, those integrated into that future milieu likely will not consider their origins, at least no more than the contemporary of today has for his or her biological beginning. But, before Darwinian evolutionary forces fully concede their superiority to the intelligent designers of tomorrow (scientists, programmers and engineers), the technologically enhanced human form will move through several uneven generations where availability will be based on affordability, geography, culture, and political and commercial interests.

For some, in-the-body devices with telemetric capability may serve to achieve and sustain a particular health-related *status quo*. For others, it will pave the way to a superior aptitude or longer, healthier lives. In still others it will be a prerequisite to a job, a career path with a necessary skill that only an embedded processor provides. The *quid pro quo* is that users will relinquish certain privacy and autonomy. At one level this may not manifest in any marked difference in how one might think about oneself. An implanted device, such as a pacemaker to contrive a heartbeat for a heart that no longer supplies one, does not change the behavior of the individual so outfitted. In ways that are socially significant, an individual, outfitted with a prosthetic limb exhibits behaviors no different than his or her un-amputated counterpart. Yet, technology similar to the pacemaker is being used to control depression, and by virtue of its clinical effect does control thinking, expression and outward behavior. A patient and his or her doctor might say for the better. And, so long as the purpose for a prosthetic is to remediate a medical dysfunction, few would have any reservations over its implementation. However, using technology to improve one's otherwise natural intellect or attained skill, through prosthetics, (e.g., leading to a mathematical quickness, business acumen, musical virtuosity, or superior athleticism), raises a number of concerns having to do with an individual's persona, not on grounds related to natural development, but through artifices that are wholly unnatural. These are matters with which the law is currently ill-equipped to fashion a remedy.

REFERENCES

[1] I coin the terms "cyborg-assisted-life" and "cyborgization" to denominate computationally-based implantable in-the-body processors of tomorrow from relatively unmodified anatomies of today.

[2] This manuscript contains commentary, data and conclusions, some of which is original and others of which has been disseminated in some significant manner in the author's recent publication, *The Techno-Human Shell-A Jump in the Evolutionary Gap* (Sunbury Press, 2012).

[3] Today's pacemaker comprises a telemetry system, an analog sensing amplifier, an analog output circuit, and a microprocessor controller. See, R. S. Sanders and M. T. Lee, Implantable pacemakers, *Proceedings of the IEEE*, vol. 84, no. 3, pp. 480-486, 1996. The leading pacemaker manufacturer Medtronic designs its microprocessors to operate on a few microamperes between 1 or 2 V. The company patterned its early microprocessors after the 16-bit RCA 1802 and Motorola 6805 microprocessors.

[4] "The CareLink® Network for pacemakers gives you the same in-depth device information as an office visit: Full Parameter Summary, Battery Voltage and Longevity, Lead Impedance and Trends, Automatic Capture Thresholds, Episodes, Percent Pacing, Histograms, Real-Time and Magnet EGMs, Stored EGMs, Arrhythmia Summary with Mode Switch Duration. **. . .** Unlike transtelephonic monitoring (TTM), CareLink transmissions provide the same device information as an in-office visit." http://www.medtronic.com/for-healthcare-professionals/products-therapies/cardiac-rhythm/patient-management-carelink/medtronic-carelink-network-for-

cardiac-device-patients/index.htm#tab4 (last visited April 28, 2012).

[5] Pacing devices, similar to the pacemaker, are used to reduce the effects of Parkinson's disease, to correct obsessive compulsive disorders, to stop tremors, reduce depression, dystonia, epilepsy, gastroparesis, obesity, bowel disorders, interstitial cystitis, urinary incontinence, and chronic back pain. Arnold J. Greenspon, et al., *Trends in Permanent Pacemaker Implantation in the United States From 1993 to 2009Increasing Complexity of Patients and Procedure* writes, "Between 1993 and 2009, 2.9 million patients received a permanent pacemaker in the United States. During this time, overall use increased by 55.6%, from 121,300 in 1993 to 188,700 in 2009. This represents 46.7 implantations per 100,000 persons in 1993, which increased to 61.6 implantations per 100,000 persons in 2009." *J Am Coll Cardiol*. 2012; 60(16):1540-1545 doi:10.1016/ j.jacc. 2012.07.017.

[6] Fukuyama argues in *Our Posthuman Future* (Fukuyama, 2002), for restrictions on the use of biotechnology for "enhancement." President George W. Bush convened the U.S. President's Council on Bioethics, under the leadership of Chairman Leon Kass, to study and critique of human enhancement medicine leading the authorship of *Beyond Therapy,* taking essentially the same position as Fukuyama, who incidentally was a member of the same commission. (President's Council on Bioethics, 2003).

[7] Dr. M.C. Roco, Chair of the U.S. National Science and Technology Council Subcommittee on Nanoscale Science, Engineering, and Technology writes: "Converging, emerging technologies refers to the synergistic combination of nanotechnology, biotechnology, information technology and cognitive sciences (NBIC), each of which is currently progressing at a rapid rate, experiencing qualitative advancements, and interacting with more established fields such as mathematics and environmental technologies." *J Nanopart Res* DOI 10.1007/s11051-007-9269-8 "Information Technology and Cognitive Science," Mihail C. Roco, citing Roco and Bainbridge, eds. (Arlington, VA: *National Science Foundation*, 2002).

[8] I have chosen the word telemetry since historically is connotes an automated communications process for collection at inaccessible points and transmitted to receiving equipment for measurement and monitoring. Although the term commonly refers to wireless it also includes POTS (telephone), optical links or other wired communications including Global System for Mobile Communications (GSM).

[9] European Medical Device Technology, March/April 2012, quoting BCC Research See, http://dc.cn.ubm-us.com/i/57632/39 (Last visited 08/05/2013).

[10] Over 6,000 US patents have issued during the past ten years typical to US pat 5,246,008, in respect of their coupling telemetry to an in-the-body device, which claims: 1. A method for monitoring a patient for rejection reactions to a transplanted heart, comprising: coupling a telemetry measuring unit implanted in the body of a patient with a telemetry control unit disposed outside the body, controllably passing an electric current from the telemetry measuring unit through the tissue of the organ via electrodes implanted in the organ, measuring the electrical impedance and transmitting a signal representative thereof to the telemetry control units, and monitoring said signal to determine the presence or absence of rejection reactions. 6, 215 patents hits were recovered from the USPTO archives using the following search criteria: ((((SPEC/(((((((anatomy OR organ) OR kidney) OR diabetes) OR intestines) OR brain) OR pacemaker) AND ((internet OR telecommunication) OR telemetry)) AND ((implant OR implanted) OR embedded)) AND ISD/20030101->20130101) AND CCL/600/$, 601/$,,602/$,,604/$,,606/$,,607/$,, 623/$). Other search criteria will produce other results, but the main proposition applies.

[11] T&S editor: Can you tell us, by what means do you believe people will be connected to the Internet in 2020? …" RK: ". . . There will be some computers that have gone inside the body, but this will not be mainstream by 2020. I would put a date such as 2030 or 2035 for that. What we will see by 2020 will be computerized devices we put inside the body largely for health interventions such as a computerized artificial pancreas. In the 2030s and 2040s, the integration of microscopic sized computerized devices will be underway and will go beyond medical applications. See, *IEEE Technology And Society Magazine*, Spring 2013, (Digital Object Identifier 10.1109/MTS.2013.2247723) Date of publication: 14 March 2013.

[12] The state of the art for today's implantable medical devices (IMD) is exemplified by US pat 8,346,360, issued Jan. 1, 2013, which states in part, "The *telemetry* link provides for data transmission from implantable medical device to external system. This includes, for example, transmitting real-time physiological data acquired by IMD, extracting physiological data acquired by and stored in IMD, extracting therapy history data stored in implantable medical device, and extracting data indicating an operational status of the IMD (e.g., battery status and lead impedance). *Telemetry* link also provides for data transmission from external system to IMD. This includes, for example, programming the IMD to acquire physiological data, programming IMD to perform at least one self-diagnostic test (such as for a device operational status), and programming the IMD to deliver at least one therapy."

[13] Medical, legal, and techno-social commentators (e.g., Kurzweil, Joy, Vinge, and others) continue to explore the ramifications of the unprecedented magnitude and rate of change of bioengineered technology on individuals, society, economics, and law related to organ transplants, drugs, DNA therapies, or stem cells—technologies that are largely biological or nature-based. Although there exists an abundance of applications for military use, this paper concentrates wholly on non military applications.

[14] Michio Kaku, *Physics of the Future*, (Anchor Books, 2012).(p.46); Also, see, Paolo Gargini, Director of Technology Strategy for Intel Corporation stated that he sees Moore's Law holding true through 2022 with current production methods. See, The Moore's Law Effect, Armed Forces Journal, http://www.armedforcesjournal.com/2010/05/4579015/(last visited, 05/17/13).

[15] H. E Kubitschek, Cell volume increase in Escherichia coli after shifts to richer media*, J. Bacteriol*. 172 (1), (January 1990).

[16] Ashton, Kevin (June 22, 2009). That 'Internet of Things' Thing, in the real world things matter more than ideas". *RFID Journal*. See, http://www.rfidjournal.com/articles/view?4986(Last visited, 05/17/2013).

[17] Waldner, Jean-Baptist (2007). *Nanoinformatique et intelligence ambiante. Inventer l'Ordinateur du XXIeme Siècle*. London: Hermes Science. pp. p254. Also, see, http://www.itu.int/osg/spu/publications/internetofthings/InternetofThings_summary.pdf.

[18] Lovell, N.H., Morley, J.W., Chen, S.C., Hallum, L.E., G.J. Suaning, G.J. (2010). Biological-machine systems integration: engineering the neural interface, *Proc. IEEE,* 98:3, 418-431. Shany, T., Redmond, S.J., Narayanan, M., Lovell, N.H. (2012). Sensors-based wearable systems for monitoring of human movement and falls, IEEE Sensors Journal, 12(3), 658-670.

[19] The word *prosthetic* is derived from the Greek word *prósthesis* meaning addition, application, or attachment which in modern times refers body part that.

[20] Although today's silicon-based microprocessor is as small as 20 microns these processors use 32 nanometer technology, which incorporate six-cores hyper- threaded chips running at roughly 3.3 gigahertz. Since each core executes two threads the theoretically processing speed is a 40 billion flops (flop is one program cycle or operation per second). Before 2020 silicon chips will use 11 nanometers technology incorporating fifty-cores allow 100 simultaneous hyper- thread to execute 330 billion flops.

[21] H. G. Noller, The Heidelberg Capsule Used For the Diagnosis of Peptic Diseases, *Aerospace Medicine*, (Feb. 1964), pp. 115-117.

[22] U.S. pat. 5,279,607.

[23] RFID Microchip-First TV Commercial, *Verichip Corp*., http://sgtreport.com/2012/06/verichip-corp-rfid-microchip-first-official-tv-commercial/ (Last visited 914/2012).

[24] Will Weissert, *Associated Press*, (7/14/2004), http://www.msnbc.msn.com/id/5439055/ns/technology_and_science-tech_and_gadgets/t/microchips-implanted-mexican-officials/.

[25] http://www.guardian.co.uk/technology/2004/jun/10/onlinesupplement1(Last visited 10/22/2012).

[26]http://www.youtube.com/watch?v=wgmraKtx7XI&feature= related (Last visited 10/22/2012)

[27] Michael S. Okun, M.D., et al., write: "DBS has provided dramatic improvements in quality of life for patients with PD, tremor, dystonia, and other movement and basal ganglia related brain disorders. As the technology is refined we will learn to improve our treatment of "motor (tremor, stiffness, slowness, balance, gait)," as well as "non-motor (mood, cognitive, and behavioral)" symptoms, perhaps in combination with other therapies." See, http://mdc.mbi.ufl.edu/surgery/am-i-a-candidate-for-deep-brain-stimulation-intro/what-is-the-future-for-deep-brain-stimulation, (Last Visited 11/07/2012).

[28] *Calling Dr. Smartphone*, Cell phone apps, help monitor blood pressure, check ears, test eyesight, gauge blood sugar. October 06, 2012 (Last visited, 05/01/2013) http://articles.latimes.com/2012/oct/06/health/la-he-health-apps-20121006.

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[30] Black Hat demo shows vulnerability of insulin pumps to remote attack, Selena Frye August 5, *2011 TechRepublic, IT Security*, http://www.techrepublic.com/blog/security/black-hat-demo-shows-vulnerability-of-insulin-pumps-to-remote-attack/6241 (Last visited, 05/17/2013).

[31] V. Sutton, *Law and Science*, Ch. 1, 2, 3 and 5. Carolina Academic Press. Also see, Reference Manual on Scientific Evidence: Third Edition. Washington, DC: *The National Academies Press*, 2011. First published by the Federal Judicial Center in 1994, the reference is used by the legal community, as both a technology and science tutorial as well as guidance on the admissibility of scientific and technical evidence. U.S. Supreme Court Justice, Stephen Breyer's provides his vision as to how technology interfaces with the law.

[32] The World Intellectual Property Organization (WIPO) with 184 member states is the United Nations agency that coordinates international treaties regarding intellectual property rights. See,http://www.giswatch.org/institutional-overview/civil-society-participation/world-intellectual-property-organisation-wipo.

[33] *Rylands V. Fletcher,* 3 HL 330 (1868).

[34] Article 2, of the Uniform Commercial Code, has been enacted statutorily enacted in nearly all 50 states, and there is innumerable cases grounded in common law actions. Additionally there are other statutes such as consumer warranty issues litigated under the federal Magnuson-Moss Warranty Act, which was enacted 30 years ago in response to the extensive misuse of warranties and disclaimers.

[35] The CDC reported that 261 persons were infected with the outbreak strains of *Salmonella* Typhimurium (228 persons) and *Salmonella* Newport (33 persons) and 94 were hospitalized, and three died. On August 22, 2012, the U.S. Food and Drug Administration (FDA) announced a recall of cantaloupes originating from Chamberlain Farms Produce,

Inc. http://www.cdc.gov/salmonella/typhimurium-cantaloupe-08-12/ (Last visited 05/07/2013).

[36] September 11th Victim Compensation Fund (9/11 victims) was created by an Act of Congress, the Air Transportation Safety and System Stabilization Act (49 USC 4010. In Re: Oil Spill by the Oil Rig "Deepwater Horizon" in the Gulf of Mexico, on April 20, 2010 USDC E.D.LA., Order And Judgment Granting Final Approval Of Medical Benefits Class Action Settlement And Confirming Certification Of The Medical Benefits Settlement Class, January 11, 2013. Also see, http://www.deepwaterhorizonsettlements.com (Last visited 08/06/2013).

[37] In January, 2007 Medtronic a leader in pacemaker technology reported five patient deaths and the FDA has 599 reports of malfunctions and injuries associated with fractured leads. Suits followed and Medtronic settled most of the cases.

[38] For an historical perspective on how the bioengineering community, industry and the federal government has seen to regulate r-DNA develop, see, Sheldon Krimsky, From Asilomar to Industrial Biotechnology: Risks, Reductionism and Regulation, *Science as Culture*, Vol. 14, No. 4, 309, 309-323, Dec. 2005.

[39] E.g., Guidelines for Research Using Human Pluripotent Stem Cells, FR, 2000.

[40] The United States Patent and Trademark Office published a revised version of guidelines to be used by Office personnel in their review of patent applications for compliance with the `utility' requirement of 35 U.S.C. 101. This revision supersedes the Revised Interim Utility Examination Guidelines that were published at 64 FR 71440, Dec. 21,1999; 1231 O.G. 136 (2000); and correction at 65 FR 3425, Jan. 21, 2000;1231 O.G. 67 (2000). The Guidelines are effective as of January 5, 2001.

[41] For medical devices, The Association for the Advancement of Medical Instruments (AAMI), Underwriters Laboratories to address device interoperability or in telecommunications, the International Organization for Standardization (ISO), the International Electrotechnical Commission (IEC), and the International Telecommunication Union (ITU).

[42] 18 U.S.C. § 506 No Electronic Theft Act; 18 U.S.C. § 1028 Identity Theft and Assumption Deterrence Act of 1998; 18 U.S.C. § 1029 Fraud and Related Activity in Connection with Access Devices; 18 U.S.C. § 1030 Fraud and Related Activity in Connection with Computers; 18 U.S.C. § 1343 Wire Fraud;18 U.S.C. § 1362 Communication Lines, Stations, or Systems;18 U.S.C. § 2511 Interception and Disclosure of Wire, Oral, or Electronic Communications Prohibited;18 U.S.C. § 2701 Unlawful Access to Stored Communications;18 U.S.C. § 2702 Disclosure of Contents;18 U.S.C. § 2703 Requirements for Governmental Access.

[43] Centers for Disease Control and Prevention, National Center for Injury Prevention and Control See, http://www.cdc.gov/injury/wisqars/fatal.html (Last visited 06/03/13).

[44] A combination product resides in the body in the form of a computer control system for: drug infusion, electrical excitation, or electronic sensing as coupled to one or more of an electrical circuit, mechanical device, or drug delivery apparatus.

[45] http://www.fda.gov/CombinationProducts/AboutCombinationProducts/ucm101464.htm (Last visited 06/03/13).

[46] There are numerous recalls related to malfunctions in medical devices with software for example, on March 6, 2013, the FDA Medical Recall Division, recalled the Alaris PC Unit (Model 8015) with Software Version 9.12 manufactured by CareFusion Corporation. The Alaris PC unit (model 8015) is part of the Alaris electronic infusion pump. An electronic infusion pump delivers controlled amounts of medications or other fluids to patients through intravenous (IV), intra-arterial (IA), epidural, and other acceptable routes of administration. The reason for the recall was that the company received reports of a communication error on the Alaris PC unit (model 8015) with software version 9.12 when the Alaris $EtCO_2$ module or Alaris SpO_2 module is attached. It reported that the use of the product may cause serious adverse health consequences, including death. See, http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm348983.htm.

[47] See, http://www.parliament.uk/business/committees/committees-a-z/commons-select/science-and-technology-committee/news/121101-medical-implants-report-published/ (Last visited 06/03/13).

[48] E.g., Yale University's policy. *HIPAA's Effect on Personal Computing and Telecommunications at Yale University* http://hipaa.yale.edu/guidance/pctelecomm.html. (Last visited 05/01/2013).

[49] For an extended discussion on the subject see, Daniel Halperin, et al, Security and Privacy for Implantable Medical Devices. *IEEE Computer Society*, Vol. 7, No. 1 January–March 2008.

[50] This paper deals with the intellectual property issues mainly from a U.S. law perspective. However, as unsettled as the matter is in the U.S., other jurisdictions also struggle to bring governance of technology in line with the speed with which it is being developed for medical applications. See, Medeva's SPC Applications [2010] EWCA Civ 700, Farmitalia Carlo Erba S.r.l.'s SPC Application (2) [2000] RPC 580, ECJ Case C-392-97.

[51] *The National Organ Transplant Act (NOTA*), makes it illegal to buy or sell organs for profit. It carries a maximum sentence of five years in prison and/or a $50,000 fine. Also see, World Health Organization, *Guiding Principle 5*, Sixty-Second World Health Assembly a62/15 Provisional Agenda item 12.10 26 March 2009.

[52] *Black's Law Dictionary* (6th ed. 1990). Property that cannot be touched because it has no physical existence such as claims, interests and rights.
[53] For example, from radio communication converged with land line telephony to bring forward the cell phone, which converged with the Internet technology to bring forth the smartphone.
[54] Under 18 U.S.C. Sec. 2510 civil liability is established for any person who—(a)intentionally intercepts, endeavors to intercept, or procures any other person to intercept or endeavor to intercept, any wire, oral, or electronic communication, etc.
[55] 18 U.S.C. Sec 1030.
56 In State Street Bank the court affirmed the so-called business methods; State Street Bank & Trust v. Signature Financial Group, Inc. 149 F.3d 1368, 47 U.S.P.Q.2d 1596.
[57] *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008).
[58] Francis Fukuyama makes a persuasive argument why he believes that future biotechnology will change human essence as well as our social reality. F. Fukuyama, *Our Posthuman Future: Consequences of the Biotechnology Revolution*, (Farrar, Straus & Giroux, 2002).
[59] The public debate, legislation, regulation and litigation over the patentability of software lasted over thirty years.
[60] In 1999, Geron Corporation Ethics Advisory Board held "hearings" on Research with human embryonic stem cells: Ethical considerations. *Hastings Center Report* 29:31-36.
[61] In certain instances, governments operating under international agreements and treaties, such as the World Trade Organization's Trade-Related Aspects of Intellectual Property Rights Agreement ("TRIPS Agreement"), and the Doha Declaration on TRIPS and Public Health permit the issuance of compulsory licenses in order to enhance social and public welfare, while protecting the interests of a patent owner. See, http://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm (Last visited 12/17/2012).
[62] By 2012 estimates, 61 million children around the world do not attend school.
[63] ". . .most scientists hold that the first organisms on Earth were much like bacteria of today…," http://www.actionbioscience.org/newfrontiers/jeffares_poole.html (Last visited, 8/7/2012).

In an era of scarce health resources, terminally ill patients, fearful of burden-ing their families, might interpret the right to die as â€œthe duty to die.â€77 Espe-. cially vulnerable are â€œthe many individuals in our society whose autonomy and. 70 Id. 71 See IAN DOWBIGGIN, A MERCIFUL END 166 (2003). Derek Humphry is the author of FINAL EXIT: THE PRACTICALITIES OF SELF-DELIVERANCE AND ASSISTED SUICIDE FOR THE DYING. First published in 1991, the book is now in a 3rd edition. Humphry founded the Hemlock Society, Id. at xvii, â€œcommitted to providing information regarding options for dignified death discussion and policy formation. 13. A plausible technological trajectory.Â As we operate in a cyborg-form a constant stream of tweets carrying sometimes. vital and sometimes non-essential queries will keep our platforms responding to the autonomous. external world (much as our Internet browsers do now).Â REGULATORY CONSIDERATIONS. In considering policy and law needed to govern implantable technology having telemetric. features, one must first address what is meant by â€œthe law.â€ Law deals with both subject matter. and process, which divides along the bright line that separates civil from criminal law. In the. U.S. and countries that have a system of common law, the foundational corpus originates in. legislation and judicial decisions. * Assistant Professor of Law, University of Richmond School of Law; Affiliated Fellow, Information Society Project. This Piece is based on remarks given at the Columbia Law Reviewâ€™s 2019 Symposium, â€œCommon Law for the Age of AI,â€ in response to Tim Wuâ€™s Lawâ€™s End? manuscript. Many thanks to BJ Ard, Douglas Bernstein, Hannah Bloch-Wehba, Jennifer Dayrit, Frank Pasquale, Richard Re, Alicia Solow-Niederman, and Harry Surden for clarifying edits and suggestions. I am also indebted to those who have thought far longer on the immediate and long-term promises and pitfalls of incorporating AI into the